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EXAMINER

KAHELIN, MICHAEL WILLIAM

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/663,570
Filing Date: September 15, 2003
Appellant(s): MONGEON ET AL.

Jessica H. Kwak
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/8/2009 appealing from the Office action mailed 1/23/2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

NEW GROUND(S) OF REJECTION

Claims 21-24, 26, 29-33, and 46 are additionally rejected in view of Heil, Jr. et al. (US 4,819,662).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

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(8) Evidence Relied Upon

4,819,662	Heil, Jr. et al.	4-1989
6,151,525	Soykan et al.	11-2000
2004/0158289	Girouard et al.	8-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

New and additional ground of rejection under 35 U.S.C. § 102(b) in view of Heil:

Claim	Limitation	Disclosure in Heil
21	A medical lead comprising:	The medical lead system is generally shown in Figures 1-7.
	A lead body;	The lead body is shown as, e.g., elements 158, 154, and 148 in Figure 7.
	A porous electrode mounted on a lead body to deliver electrical stimulation to a stimulation site within a patient; and	The electrode is shown as element 150 in Figure 7 and described as porous at column 6, line 50.
	A chamber body that defines a chamber, the chamber containing a polymeric matrix that absorbs genetic material and elutes the genetic material to tissue at the stimulation site via the porous electrode, wherein the genetic material is adapted to cause expression of at least one of a connexin or a gap junction by the tissue at the stimulation site to increase the conductivity of the tissue at the stimulation site.	The chamber body is shown as element 168 in Figure 7 and contains a polymeric (silicone) matrix 170. This is further described at column 4, lines 45-49 and column 6, lines 49-66. As the genetic material is not positively recited, Heil's matrix is capable of meeting the claim limitations as silicone is capable of absorbing genetic material. See Soykan at column 11, line 49.

Previous ground of rejection under 35 U.S.C. 103(a) in view of Soykan, Heil, and

Girouard:

Claim	Limitation	Disclosure in prior art	Reason to modify
21	A medical lead	Soykan's medical lead system is	

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	comprising:	generally described at column 13, lines 38-54.	
	A lead body;	Soykan's lead body is described at, e.g., col. 13, lines 49-54.	
	A porous electrode mounted on a lead body to deliver electrical stimulation to a stimulation site within a patient; and	Heil teaches a system having a porous electrode mounted on a lead body as element 150 in Figure 7.	To provide controlled release of pharmacological agents at the site of electrical therapy.
	A chamber body that defines a chamber, the chamber containing a polymeric matrix that absorbs genetic material and elutes the genetic material to tissue at the stimulation site via the porous electrode,	Soykan discloses that the genetic material is eluted using a silicone polymeric matrix at column 11, line 49, and Heil discloses a chamber body shown as element 168 in Figure 7 that contains a polymeric (silicone) matrix 170. This is further described by Heil at column 4, lines 45-49 and column 6, lines 49-66.	To provide controlled release of pharmacological agents at the site of electrical therapy.
	Wherein the genetic material is adapted to cause expression of at least one of a connexin or a gap junction by the tissue at the stimulation site to increase the conductivity of the tissue at the stimulation site.	Girouard teaches causing expression of connexin by the treated tissue at the stimulation site by application of a genetic material at paragraph 0146.	To repair damaged heart tissue.

NEW GROUNDS OF REJECTION IN VIEW OF HEIL:***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 23, 24, 26, 29-33, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Heil.

In regards to claim 21, Heil discloses a lead body (158, 154, and 148), a porous electrode (150), and a chamber body containing a polymeric matrix that is capable of eluting a genetic material (168). Please note that claim 21 does NOT positively recite the genetic material. Further, Heil's matrix is capable of meeting the claim limitations as silicone is capable of absorbing genetic material. See Soykan at column 11, line 49.

In regards to claim 23, silicone is a cross-linked material and the elution rate is necessarily a function of the cross-linking because more cross-links result in larger mechanical resistance to elution.

In regards to claim 24, the body is separable for loading the matrix and genetic material (col. 7, lines 5-9).

In regards to claims 26, 29, 30, 31, and 46, the matrix is capable of being loaded with genetic materials, including those claimed. See Soykan at column 11, line 49. As the genetic material is not positively recited, these claims limit only the structure of the matrix itself.

In regards to claims 32, the electrode is implantable within a patient and the stimulation site is cardiac tissue (abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heil in view of Soykan. Heil discloses the essential features of the claimed invention except for indicating that the matrix comprises extracellular collagen. However, Soykan teaches that it is known in the art to elute drugs and genetic material using extracellular collagen (col. 11, line 47) to provide the predictable result of a natural drug delivery material that allows for controlled chronic drug or genetic material delivery. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Heil's invention by providing a matrix comprising extracellular collagen to provide the predictable result of a natural drug delivery material that allows for controlled chronic drug or genetic material delivery.

**PREVIOUS GROUNDS OF REJECTION IN VIEW OF SOYKAN, HEIL, AND
GIROUARD:**

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-24, 26, 29-33, 35-42 and 46 are rejected under 35 U.S.C. 103(a) as obvious over Soykan in view of Heil, Jr. et al. (US 4,819,662, hereinafter "Heil") and Girouard et al. (US 2004/0158289, hereinafter "Girouard").

In regards to claims 21, 24, 36, and 46, Soykan discloses a method/system comprising a lead for delivering electrical stimulation to tissue (col. 13, line 38) and eluting genetic material from a polymeric matrix (col. 11, line 1) to cause transgenic expression that increases the conductivity at the stimulation site. Increasing the contractile ability of the stimulation area (from cells that do not contract at all, per column 1, lines 57-58, to cells that contract, per the abstract of the disclosure) inherently increases the conductivity because non-contractile cells do not have the membrane proteins that allow for cell contraction, while contractile cells do have these proteins. This inherent and fundamental feature of these cells means that the conductivity is increased in the region of these new cells. Further, this increase in contractile ability inherently creates some preferential conduction pathway between the stimulation site

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and at least one of a bundle of His or a Purkinje fiber because the applied pulse or propagating action potential must follow some preferred path created by the improved conductivity of the treated region of the heart. For example, referring to Figure 1, after treatment, action potentials generated in the newly treated region will flow through a different path than when the tissue was not fully-functioning contractile heart tissue. Soykan does not disclose a chamber that elutes material from a porous electrode or that the genetic material causes expression of connexin or a gap-junction. Heil teaches of providing a lead with a removable chamber that elutes substances through a porous electrode for the purpose of providing controlled release of pharmacological agents at the site of electrical therapy (abstract, Fig. 7). Further, Girouard teaches providing a cardiac therapy comprising delivering connexin for the purpose of repairing damaged heart tissue (par. 0146). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Soykan's invention by providing a lead with a chamber that elutes substances through a porous electrode for the purpose of providing controlled release of pharmacological agents at the site of electrical therapy and providing a cardiac therapy comprising delivering connexin for the purpose of repairing damaged heart tissue.

In regards to claim 22, Soykan discloses that the matrix is extracellular collagen (col. 11, line 47).

In regards to claims 23 and 37, the matrix is cross-linked (col. 11, line 55). The level of cross-linking is inherently proportional to the release rate.

In regards to claims 26, the delivery vector is a liposome (claim 7).

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In regards to claims 32, the electrode is implantable (col. 13, line 49).

In regards to claims 33, the tissue is cardiac tissue (abstract).

Claims 36 and 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan in view of Heil and Girouard. Soykan's modified invention discloses the essential features of the claimed invention, including using autologous biological material (col. 5, line 67) that is incorporated just prior to delivery by swelling the hydrogel (col. 11, line 59), but does not disclose a freeze-dried (lyophilized) or frozen matrix, a genetic material that causes expression of a metalloproteinase, an anti-inflammatory agent, or an immunosuppressant agent, placing the matrix in the lead just before implantation, or soaking of the distal end of the lead in the genetic material. It is well known in the art to freeze-dry or freeze matrix to increase the shelf-life of the biologically active substance, to provide genetic materials that cause expression of a metalloproteinase, an anti-inflammatory agent, or an immunosuppressant agent to reduce rejection complications in a host patient, and to soak (or swell) matrix in genetic material before placement into the body (either before delivery, or right at delivery) to allow autologous biological substances to be implanted. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Soykan's invention by freeze-drying or freezing matrix to provide the predictable result of increasing the shelf-life of the biologically active substance, to provide genetic materials that cause expression of a metalloproteinase, an anti-inflammatory agent, or an immunosuppressant agent to provide the predictable result of

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reducing rejection complications in a host patient and soaking matrix in genetic material before placement into the body to provide the predictable result of allowing autologous biological substances to be implanted.

(10) Response to Argument

CLAIMS 21-24, 26, AND 29-33

Appellant argued that the combination of Soykan, Heil, and Girouard under 35 U.S.C. 103(a) lacks a rational underpinning because an artisan of ordinary skill would not be motivated to apply Heil's lead configuration to Soykan's system to provide "controlled release of pharmacological agents at the site of electrical therapy" because Soykan's system already does this, as shown by Soykan's disclosure at column 11, lines 5-7 (indicating that the genetic material may be incorporated into a carrier, which may be an electrical stimulation device). However, Soykan is silent as to precisely where on or in the electrical stimulation device the carrier resides. Heil is provided as a teaching of one of many prior-art configurations wherein the therapeutic agent carrier is a porous electrode. Because of Soykan's silence concerning the *specific* location on the device for the carrier, the Examiner maintains the position that looking to prior art carrier configurations, such as Heil's, would require only ordinary skill in the art. The Examiner further maintains that an artisan of ordinary skill would be motivated to make this modification to provide the agent *at the site of electrical therapy*. Heil provides the therapeutic agent to, e.g., "reduce the problem of acute stimulation threshold increase" and "counter[] chronic threshold increase" (col. 2, lines 35-40); both of which are phenomena associated with the electrode-body interface of the stimulation system.

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Soykan's genetic agent provides for increasing the contractility of cardiac tissue (abstract) and stimulating those very cells with the electrical stimulation system. The Examiner maintains the position that an artisan of ordinary skill would be motivated to modify Soykan's invention by providing the agent at the site of electrical stimulation, as taught by Heil, because the cells that are the target of the therapeutic agent are the same cells that are the target of the electrical therapy. Furthermore, while a teaching, suggestion, or motivation is sufficient to render the combination obvious, it is not necessary. See *KSR*. An alternative basis is a showing that the combination is a simple substitution of one known element for another to obtain predictable results. The Examiner maintains that the modification of Soykan's electrical stimulation device by providing the known lead structure of Heil would be an example of such "simple substitution" as the interchangeability of leads and electrical stimulators is known in the art.

Appellant further argued that the combination of Soykan and Heil does not render predictable results because drugs and genetic materials have different purposes and properties, such as the effects of genetic materials lasting longer and being more localized. However, the Examiner maintains that placing the genetic material-eluting polymeric matrix of Soykan into the chamber of Heil's lead specifically designed to provide elution of therapeutic agents through the electrode would render predictable results because the electrode provides "free fluid flow" (col. 2, lines 38-41). The Examiner's position is that this "free flow" indicates that agents will diffuse, whether genetic material or drugs. It is noted that Appellant has not disclosed that diffusion of

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genetic material through the porous electrode requires more than mere fluid communication (e.g., paragraph 0030).

Appellant further argued that the combination of Girouard is also erroneous because the Girouard's genetic material is applied to cells *in vitro*, and the cells are later administered to the patient, while Soykan provides genetic material directly to the patient's cells within the body. Referring to paragraph 0044, Girouard recognizes that the vectors may be applied either *in vitro* or *in vivo*. The Examiner maintains that an artisan of ordinary skill could have predictably applied Girouard's teaching of providing genetic material that causes the expression of connexin to Soykan's system. Soykan's system utilizes, e.g., a viral or liposome vector incorporated into a carrier (col. 11, lines 1-7) to create or repopulate contractile cells. Girouard has identified genetic material that causes the expression of connexin, identified that this genetic material is useful for improving the contractility of heart tissue, and has isolated this genetic material in a delivery vector. Although Girouard may not disclose that the genetic material is directly applied to cells in the heart, Girouard is not relied upon for this teaching, as Soykan provides genetic material directly to cells within the heart. Girouard is relied upon merely for teaching the specific genetic material recognized as useful for improving cardiac tissue contractility. Appellant has provided no evidence that this material isolated in vector form is somehow unusable *in vivo*, and Girouard discloses the contrary (par. 0044). Moreover, Girouard's disclosure that the material is isolated and provided in a vector similar to those used by Soykan, and that the vector is usable *in vivo* indicate that an artisan of ordinary skill could have predictably substituted

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Girouard's genetic material-containing vector for the genetic material-containing vector of Soykan's carrier.

CLAIM 46

Appellant argued that Soykan's disclosure of converting non-contractile cells to contractile cells does not create a "preferential conduction pathway" because the new contractile cells may create a path that is the same or less preferred to another pathway. Appellant further reasoned that, although the conversion of non-contractile cells to contractile cells may improve the conduction pathway compared to the pathway that existed prior to the conversion, this does not necessarily result in a pathway that is more preferred over other pathways between the stimulation site and the bundle of His or Purkinje fiber. However, the claim does not require the optimum, shortest (or even shorter) pathway, and does not indicate who or what "prefers" the new conduction pathway. As the current (or action potential) necessarily follows a new path because of the new contractile tissue, this path is "preferred" by the current or action potential to the previous path.

CLAIMS 35-42

The reasoning applied to claim 21 likewise applies to these claims.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

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Respectfully submitted,

/Michael Kahelin/

Examiner, Art Unit 3762

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/DONALD HAJEC/

Director, Technology Center 3700

Conferees:

/George R Evanisko/

Primary Examiner, Art Unit 3762

/Angela D Sykes/

Supervisory Patent Examiner, Art Unit 3762